



UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY, DOCKET NO.
07/188,051	11/06/98	SHIRLEY	100

000826
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HM12/1013

MOE ZIE	EXAMINER
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ART UNIT	PAPER NUMBER
1-54	

DATE MAILED: 10/13/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/188,051

Applicant(s)

Shirley et al.

Examiner

F. Moesie

Group Art Unit

1654

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE One MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 07/16/99
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1-28 is/are pending in the application.
- Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☐ Claim(s) _____ is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☒ Claim(s) 1-28 are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
- ☐ received in Application No. (Series Code/Serial Number) _____.
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other _____

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DETAILED ACTION

The response filed 16 July 1999, paper no. 9, has been made of record.

Claims 1-20 have originally been filed. Claims 1, 2, 5, 8, 11, 12, 15, 17 and 20 have been amended and the new claims 21-28 have been added. Hence, claims 1-28 are currently pending prosecution in this Office Action.

Upon further consideration and search regarding the amended and the newly added claims, the following Restriction Requirement and Species Election are deemed proper. Accordingly, the previous action is withdrawn.

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-17, drawn to a composition and a method of making the same - comprising IGF-I, classified in class 530, subclass 303, for example.
- II. Claims 1-17, drawn to a composition and a method of making the same - comprising an IGF-I analog wherein the analog is a compound that retains IGF-I activity, classified in class 530, subclass depending on the structure of the elected analog.
- III. Claims 1-17, drawn to a composition comprising an IGF-I analog wherein the analog is a compound that binds an IGF-I receptor and a method of making the

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composition, classified in class 530, subclass depending on the structure of the elected analog.

- IV. Claims 1-17, drawn to a composition comprising an IGF-I analog wherein the analog retains IGF-I activity and binds an IGF-I receptor and a method of making the composition, classified in class 530, subclass depending on the structure of the elected analog.
- V. Claims 18 and 19, drawn to a method of delivering IGF-I or an IGF-I analog to a subject, classified in class 514, subclass 12, for example.
- VI. Claims 20-28, drawn to a method of enhancing or stabilizing the solubility of a composition comprising IGF-I or an IGF-I analog, classified in class 530, subclass depending on the elected analog.

The inventions are distinct, each from the other because of the following reasons:

Inventions I, II, III or IV are distinct one from the other. Group I invention is drawn to a composition wherein the active ingredient in the composition is IGF-I. Groups II, III or IV are drawn to a composition wherein the active compound is an analog of IGF-I. The analog in each group of invention imparts a distinct quality or function to the composition as claimed. Thereby each analog must have its own unique structural, conformational, physical and chemical properties so that it can impart the claimed activity or function to the composition. Hence, the elected structure would determine the particular search area for the analog intended in the claim(s).

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Inventions I, II, III, or IV and V or VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process of using the product can be practiced with another materially different product such as insulin or insulin analogs.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Upon allowance of claim(s) to invention I, II, III or IV, Examiner will rejoin one method of use for the allowable composition provided that the use is commensurate in scope with the allowed invention.

Election of Species

Claims 1-28 are generic to a plurality of disclosed patentably distinct species comprising: (A) species of IGF-I analog and (B) species of solubilizing compound. Applicant is required under 35 U.S.C. 121 to elect a single disclosed specie from (A) and from (B), even though this requirement is traversed.

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Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

A "specie" is a specific compound, with all substituent variables fully accounted for.

A telephone call was made to Mr. Spruill on 18 August 1999 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention together with an election of specie (A), if applicable, and specie (B), to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner F.T. Moezie whose telephone number is (703) 305-4508 or Mr. Woodward (SPE) at 308-4028.

F.T. Moezie
F. T. MOEZIE, Ph.D.
PRIMARY EXAMINER
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